

We claim:

1. A process for assisting the function of a heart disposed within a body, and comprising an outer wall, said process comprising the steps of:
  - a. measuring at least one parameter that is indicative of said function of said heart;
  - 5 b. applying a compressive force to a portion of said outer wall of said heart; and
  - c. applying an expansive force to said portion of said outer wall of said heart.
2. The process as recited in claim 1, wherein said at least one measured parameter is selected from the group consisting of left ventricular blood pressure, left atrial blood pressure, aortic blood pressure, right ventricular blood pressure, right atrial blood pressure, pulmonary blood pressure, left ventricle volume, right ventricle volume, aortic
   
10 blood flow rate, pulmonary blood flow rate, left ventricular blood flow velocity, aortic blood flow velocity, right ventricular blood flow velocity, pulmonary blood flow velocity, cardiac core diameter, lactate concentration, cytokine concentration, parathormone concentration, nitric oxide concentration, free-oxygen radical concentration,
   
15 metalloproteinase concentration, C-reactive protein concentration, oxygen concentration, carbon dioxide concentration, an electrical potential across at least a portion of said heart, and an electrical current through at least a portion of said heart
3. The process as recited in claim 1, further comprising the step of measuring a 2<sup>nd</sup> parameter that is indicative of said function of said heart.
- 20 4. The process as recited in claim 3, further comprising the step of measuring a 3<sup>rd</sup> parameter that is indicative of said function of said heart.
5. The process as recited in claim 1, wherein said at least one measured parameter is aortic blood pressure.
6. The process as recited in claim 5, further comprising the step of measuring cardiac
   
25 ejection fraction.
7. The process as recited in claim 1, further comprising the step of controlling the magnitude of said compressive force based upon said parameter.
8. The process as recited in claim 1, further comprising the step of controlling the magnitude of said expansive force based upon said parameter.
- 30 9. The process as recited in claim 8, wherein said compressive force is used to assist systolic compression of said heart.

10. The process as recited in claim 9, wherein said expansive force is used to assist diastolic expansion of said heart.
11. The process as recited in claim 10, wherein said magnitude of said compressive force is applied uniformly over said portion of said outer wall of said heart.
- 5 12. The process as recited in claim 11, wherein the direction of said compressive force applied over said portion of said outer wall of said heart is perpendicular to said outer wall of said heart.
13. The process as recited in claim 12, wherein said compressive force is applied by applying a pressure to said portion of said outer wall of said heart.
- 10 14. The process as recited in claim 13, wherein said pressure is applied to said portion of said outer wall of said heart by applying said pressure to a liner that is contiguous with said portion of said outer wall of said heart.
15. The process as recited in claim 14, wherein said pressure is applied to said liner by a fluid in contact with said liner.
- 15 16. The process as recited in claim 15, wherein said fluid is a gas.
17. The process as recited in claim 15, wherein said fluid is a liquid.
18. The process as recited in claim 15, wherein said expansive force is applied by applying a vacuum to said portion of said outer wall of said heart.
19. The process as recited in claim 18, wherein said vacuum is applied to said liner by said  
20 fluid in contact with said liner.
20. The process as recited in claim 19, wherein said fluid is a gas.
21. The process as recited in claim 19, wherein said fluid is a liquid.
22. The process as recited in claim 19, wherein said step of applying a compressive force to said portion of said outer wall of said heart comprises the substeps of:
  - 25 a. beginning the displacement of blood from the right ventricle of said heart;
  - b. beginning the displacement of blood from the left ventricle of said heart while continuing said displacement of blood from said right ventricle of said heart;
  - c. ceasing the displacement of blood from said right ventricle of said heart while continuing said displacement of blood from said left ventricle of said heart; and
  - 30 d. ceasing the displacement of blood from said left ventricle of said heart.
23. The process as recited in claim 22, wherein said step of applying an expansive force to said portion of said outer wall of said heart comprises the substeps of:

- a. beginning the intake of blood into said right ventricle and said left ventricle of said heart;
- b. continuing the intake of blood into said right ventricle and said left ventricle of said heart; and
- 5 c. ceasing the intake of blood into said right ventricle and said left ventricle of said heart.

24. The process as recited in claim 23, wherein said expansive force is applied to said portion of said outer wall of said heart by applying a vacuum to said portion of said outer wall of said heart.

10 25. The process as recited in claim 23, further comprising the step of applying no force to said portion of said outer wall of said heart for a time period of between about zero seconds and about one second.

15 26. The process as recited in claim 25, further comprising the repeating at least one time of said steps of applying said compressive force to said portion of said outer wall of said heart, applying said expansive force to said portion of said outer wall of said heart, and applying said no force to said portion of said outer wall of said heart for said time period of between about zero seconds and about one second.

20 27. The process as recited in claim 22, wherein after said substep of ceasing the displacement of blood from said left ventricle of said heart, the core diameter of said heart is less than about one-third and about one half of the maximum diameter of said heart above said core diameter, and less than about one half and two thirds of the maximum diameter of said heart below said core diameter of said heart.

28. The process as recited in claim 27, wherein the cross-sectional shape of said heart at said core diameter thereof is substantially circular.

25 29. An apparatus for assisting the function of a heart disposed within a body, and comprising an outer wall, said apparatus comprising:

- a. a cup-shaped shell having an exterior wall, an interior wall, an apex, and an upper edge;
- b. a liner having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell, thereby forming a cavity between said outer surface thereof and said interior wall of said shell; and
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- c. a drive fluid cyclically interposed within said cavity, said drive fluid applying a uniform force on a portion of said outer wall of said heart.
30. The apparatus as recited in claim 29, wherein said liner is an elastic liner.
31. The apparatus as recited in claim 30, wherein said elastic liner is silicone polymer.
- 5 32. The apparatus as recited in claim 29, wherein said liner is biocompatible.
33. The apparatus as recited in claim 29, wherein said liner is biodegradable.
34. The apparatus as recited in claim 29, wherein said liner is detachable from said interior wall of said cup shaped shell.
35. The apparatus as recited in claim 29, wherein said liner comprises a first therapeutic agent.
- 10 36. The apparatus as recited in claim 35, wherein said first therapeutic agent is diffused throughout said liner.
37. The apparatus as recited in claim 35, wherein said first therapeutic agent comprises a coating on said inner surface of said liner.
- 15 38. The apparatus as recited in claim 35, wherein said liner comprises a first membrane and a second membrane, and said first therapeutic agent is disposed between said first membrane and said second membrane.
39. The apparatus as recited in claim 35, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
- 20 40. The apparatus as recited in claim 35, wherein said liner is detachable from said interior wall of said cup shaped shell.
- 25 41. The apparatus as recited in claim 35, wherein said liner comprises a second therapeutic agent.
42. The apparatus as recited in claim 29, wherein said liner has a textured inner surface.
43. The apparatus as recited in claim 29, wherein said liner comprises a first membrane having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell; and a second membrane having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said
- 30

interior wall of said cup-shaped shell; and wherein said inner surface of said first membrane is contiguous with said outer surface of said second membrane.

44. The apparatus as recited in claim 29, wherein said liner is a rolling diaphragm liner.

45. The apparatus as recited in claim 44, wherein said rolling diaphragm liner consists  
5 essentially of heat cured liquid silicone rubber.

46. The apparatus as recited in claim 44, wherein said rolling diaphragm liner is biocompatible.

47. The apparatus as recited in claim 44, wherein said rolling diaphragm liner is biodegradable.

10 48. The apparatus as recited in claim 44, wherein said rolling diaphragm liner is detachable from said interior wall of said cup shaped shell.

49. The apparatus as recited in claim 44, wherein said rolling diaphragm liner comprises a first therapeutic agent.

50. The apparatus as recited in claim 49, wherein said first therapeutic agent is diffused  
15 throughout said rolling diaphragm liner.

51. The apparatus as recited in claim 49, wherein said first therapeutic agent comprises a coating on said inner surface of said rolling diaphragm liner.

52. The apparatus as recited in claim 49, wherein said rolling diaphragm liner comprises a first membrane and a second membrane, and said first therapeutic agent is disposed  
20 between said first membrane and said second membrane.

53. The apparatus as recited in claim 49, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents,  
25 imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.

54. The apparatus as recited in claim 49, wherein said rolling diaphragm liner is detachable from said interior wall of said cup shaped shell.

55. The apparatus as recited in claim 49, wherein said rolling diaphragm liner comprises a second therapeutic agent.

30 56. The apparatus as recited in claim 49, wherein said rolling diaphragm liner has a textured inner surface.

57. The apparatus as recited in claim 29, wherein said liner comprises a first membrane having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell; and a second membrane having an outer surface and an inner surface, an upper edge  
5 joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell; and wherein said inner surface of said first membrane is contiguous with said outer surface of said second membrane.
58. The apparatus as recited in claim 44 further comprising a seal comprising a base joined to said upper edge of said cup-shaped shell, a tapered midsection, and a tip.
- 10 59. The apparatus as recited in claim 58, wherein said rolling diaphragm liner and said seal are unitary.
60. The apparatus as recited in claim 59, wherein said rolling diaphragm liner and said seal are formed by a molding process.
61. The apparatus as recited in claim 59, wherein said rolling diaphragm liner and said seal  
15 consist essentially of heat cured liquid silicone rubber.
62. The apparatus as recited in claim 59, wherein said seal further comprises means for deploying said tip of said seal contiguously with said outer wall of said heart.
63. The apparatus as recited in claim 62, wherein said means for deploying said tip of said seal contiguously with said outer wall of said heart comprises a ring disposed proximate  
20 to said tip of said seal, and a mating groove disposed in said exterior wall of said shell proximate to said upper edge of said shell.
64. The apparatus as recited in claim 63, wherein said means for deploying said tip of said seal contiguously with said outer wall of said heart further comprises a cavity disposed within said tapered midsection of said seal, and a lumen connected to said cavity and to a  
25 fluid source.
65. The apparatus as recited in claim 58, wherein said seal is biocompatible.
66. The apparatus as recited in claim 58, wherein said seal is biodegradable.
67. The apparatus as recited in claim 58, wherein said seal is detachable from said upper edge of said cup-shaped shell.
- 30 68. The apparatus as recited in claim 58, wherein said seal comprises a first therapeutic agent.
69. The apparatus as recited in claim 68, wherein said first therapeutic agent is diffused throughout said seal.

70. The apparatus as recited in claim 68, wherein said first therapeutic agent comprises a coating on the outer surface of said seal.
71. The apparatus as recited in claim 68, wherein a cavity is disposed within said seal, and said first therapeutic agent is disposed within said cavity.
- 5 72. The apparatus as recited in claim 68, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
- 10 73. The apparatus as recited in claim 68, wherein said seal comprises a second therapeutic agent.
74. The apparatus as recited in claim 58, wherein said seal has a textured outer surface.
75. The apparatus as recited in claim 58, wherein said liner comprises a first membrane having an outer surface and an inner surface, an upper edge joined to said interior wall of  
15 said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell; and a second membrane having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell; and wherein said inner surface of said first membrane is contiguous with said outer surface of said second membrane.
- 20 76. The apparatus as recited in claim 29, wherein said cup shaped shell comprises a hollow wall structure comprised of alternating ribs and cavities.
77. The apparatus as recited in claim 76, wherein said cup shaped shell further comprises an inner shell wall and an outer shell wall, and said ribs are joined to said inner shell wall and to said outer shell wall.
- 25 78. The apparatus as recited in claim 77, wherein said ribs are aligned from said upper edge of said cup shaped shell toward said apex of said cup shaped shell.
79. The apparatus as recited in claim 77, wherein said ribs are aligned circumferentially around said cup shaped shell.
80. The apparatus as recited in claim 77, wherein said ribs are formed in a unitary structure  
30 with said inner shell wall.
81. An apparatus for assisting the function of a heart disposed within a body, and comprising an outer wall, said apparatus comprising:

- a. a cup-shaped shell having an exterior surface and an interior surface;
- b. a liner having an outer surface, an upper edge joined to said interior surface of said cup-shaped shell, and a lower edge joined of said interior surface of said cup-shaped shell, thereby forming a cavity between said outer surface thereof and said interior surface of said shell;
- c. a drive fluid cyclically interposed within said cavity; and
- d. at least one sensor measuring at least one parameter.

82. The apparatus as recited in claim 81, wherein said at least one sensor comprises means for generating ultrasonic energy, and means for receiving ultrasonic energy.

83. The apparatus as recited in claim 82, further comprising means for producing an image from ultrasonic energy received by said means for receiving ultrasonic energy.

84. The apparatus as recited in claim 83, wherein said ultrasonic sensor is disposed in said apex of said cup shaped shell.

85. The apparatus as recited in claim 83, wherein at least one of said cup-shaped shell, said liner, and said drive fluid comprises an imaging contrast agent.

86. The apparatus as recited in claim 82, wherein said cup-shaped shell further comprises a plurality of sensors comprising means for generating ultrasonic energy, and means for receiving ultrasonic energy.

87. The apparatus as recited in claim 83, wherein said plurality of sensors is disposed between said exterior surface and said interior surface of said shell.

88. The apparatus as recited in claim 83, wherein said plurality of sensors is disposed on said exterior surface of said shell.

89. The apparatus as recited in claim 83, wherein said plurality of sensors is disposed on said interior surface of said shell.

90. The apparatus as recited in claim 81, wherein said at least one sensor comprises an integrated magnetic resonance transmit and receiver coil.

91. The apparatus as recited in claim 90, further comprising means for producing an image from magnetic resonance data received by said integrated magnetic resonance coil.

92. The apparatus as recited in claim 91, wherein said integrated magnetic resonance coil is disposed between said exterior surface and said interior surface of said cup-shaped shell.

93. The apparatus as recited in claim 91, wherein said integrated magnetic resonance coil is disposed within a support ring formed on the exterior surface of said cup-shaped shell.



94. The apparatus as recited in claim 91, wherein at least one of said cup-shaped shell, said liner, and said drive fluid comprises an imaging contrast agent.
95. The apparatus as recited in claim 81, wherein said at least one sensor is an electrophysiological sensor.
- 5 96. The apparatus as recited in claim 95, wherein said electrophysiological sensor is disposed on said interior surface of said cup shaped shell.
97. The apparatus as recited in claim 95, wherein said cup-shaped shell further comprises a plurality of electrophysiological sensors
98. The apparatus as recited in claim 97, wherein said plurality of electrophysiological  
10 sensors is disposed on said interior surface of said shell.
99. The apparatus as recited in claim 95, wherein said liner further comprises a plurality of electrophysiological sensors
100. The apparatus as recited in claim 81, wherein said at least one sensor is a pressure sensor.
- 15 101. The apparatus as recited in claim 100, wherein said at least one pressure sensor is disposed within said cavity.
102. The apparatus as recited in claim 100, wherein said at least one pressure sensor is disposed on said interior surface of said cup-shaped shell.
103. The apparatus as recited in claim 100, wherein said at least one pressure sensor is  
20 disposed within said liner.
104. The apparatus as recited in claim 100, wherein said at least one pressure sensor is disposed on said outer surface of said liner.
105. The apparatus as recited in claim 100, wherein said drive fluid is cyclically interposed into said cavity through a lumen in communication in said cavity, and wherein said at  
25 least one pressure sensor is disposed within said lumen.
106. The apparatus as recited in claim 100, further comprising a second pressure sensor.
107. The apparatus as recited in claim 81, wherein said at least one sensor is a flow sensor.
108. The apparatus as recited in claim 107, wherein said at least one flow sensor is disposed within said cavity.
- 30 109. The apparatus as recited in claim 107, wherein said at least one flow sensor is disposed on said interior surface of said cup-shaped shell.

110. The apparatus as recited in claim 107, wherein said at least one flow sensor is disposed within said liner.
111. The apparatus as recited in claim 107, wherein said at least one flow sensor is disposed on said outer surface of said liner.
- 5 112. The apparatus as recited in claim 107, wherein said drive fluid is cyclically interposed into said cavity through a lumen in communication in said cavity, and wherein said at least one flow sensor is disposed within said lumen.
113. The apparatus as recited in claim 81, wherein said at least one sensor comprises means for sensing the position of said liner relative to said interior surface of said cup-shaped  
10 shell.
114. The apparatus as recited in claim 113, wherein said means for sensing said position comprises a Hall effect sensor.
115. The apparatus as recited in claim 113, wherein said means for sensing said position comprises a magnetic slug disposed on said outer surface of said liner, and a magnetic  
15 proximity pickup disposed on said interior surface of said shell.
116. The apparatus as recited in claim 113, wherein said means for sensing said position comprises a light source and photodetector.
117. The apparatus as recited in claim 81, wherein said liner is detachable from said interior wall of said cup shaped shell.
- 20 118. The apparatus as recited in claim 81, wherein said liner comprises a first therapeutic agent.
119. The apparatus as recited in claim 118, wherein said first therapeutic agent is diffused throughout said liner.
120. The apparatus as recited in claim 118, wherein said first therapeutic agent comprises a  
25 coating on said inner surface of said liner.
121. The apparatus as recited in claim 118, wherein said liner comprises a first membrane and a second membrane, and said first therapeutic agent is disposed between said first membrane and said second membrane.
122. The apparatus as recited in claim 118, wherein said first therapeutic agent is selected  
30 from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell

engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.

123. The apparatus as recited in claim 118, wherein said liner is detachable from said interior wall of said cup shaped shell.

5 124. The apparatus as recited in claim 118, wherein said liner comprises a second therapeutic agent.

125. The apparatus as recited in claim 81, wherein said liner is a rolling diaphragm liner.

126. The apparatus as recited in claim 125, wherein said rolling diaphragm liner consists essentially of heat cured liquid silicone rubber.

10 127. The apparatus as recited in claim 125, wherein said rolling diaphragm liner is biocompatible.

128. The apparatus as recited in claim 125, wherein said rolling diaphragm liner is biodegradable.

15 129. The apparatus as recited in claim 125, wherein said rolling diaphragm liner is detachable from said interior wall of said cup shaped shell.

130. The apparatus as recited in claim 125, wherein said rolling diaphragm liner comprises a first therapeutic agent.

20 131. A process for assisting the function of a heart disposed within a living body of a patient, and comprising an outer wall, said process utilizing a controller and comprising the steps of:

- a. importing at least one value of at least one parameter relating to said function of said heart into said controller;
- b. using an algorithm to formulate at least one command instruction, based upon said at least one value of said one parameter; and
- 25 c. exporting said at least one command instruction from said controller.

132. The process as recited in claim 131, wherein said at least one parameter is input by said patient.

133. The process as recited in claim 131, wherein said at least one parameter is input by a physician.

30 134. The process as recited in claim 131, wherein said at least one parameter is a therapeutic response factor.

135. The process as recited in claim 131, wherein said at least one parameter is an electrophysiological parameter.

136. The process as recited in claim 131, wherein said at least one parameter is a three-dimensional data array of electrophysiological parameters.

5 137. The process as recited in claim 131, wherein said at least one parameter is a biochemical marker.

138. The process as recited in claim 137, wherein said biochemical marker is selected from the group consisting of lactate, C-reactive protein, oxygen, and carbon dioxide.

10 139. The process as recited in claim 131, wherein said at least one parameter is blood pressure.

140. The process as recited in claim 131, wherein said at least one parameter is blood flow velocity.

141. The process as recited in claim 131, wherein said at least one parameter is cardiac ejection fraction.

15 142. The process as recited in claim 131, wherein said at least one parameter is inferred from ultrasonic image data.

143. The process as recited in claim 142, wherein said at least one parameter inferred from ultrasonic image data is right ventricle volume.

20 144. The process as recited in claim 142, wherein said at least one parameter inferred from ultrasonic image data is left ventricle volume.

145. The process as recited in claim 131, wherein said at least one parameter is inferred from magnetic resonance image data.

146. The process as recited in claim 145, wherein said at least one parameter inferred from magnetic resonance image data is right ventricle volume.

25 147. The process as recited in claim 145, wherein said at least one parameter inferred from magnetic resonance image data is left ventricle volume.

148. The process as recited in claim 131, wherein said at least one parameter is a numerical values that quantifies a prior aspect of said patient.

30 149. The process as recited in claim 131, wherein said at least one parameter is predictive parameter of said patient.

150. The process as recited in claim 131, further comprising the step of importing at least one value of a second parameter.

151. The process as recited in claim 131, wherein said heart is assisted by a direct mechanical ventricular assistance apparatus operated by displacement a drive fluid.
152. The process as recited in claim 151, further comprising the step of importing at least one value of at least one parameter of said direct mechanical ventricular assistance apparatus.
153. The process as recited in claim 152, wherein said at least one parameter of said direct mechanical ventricular assistance apparatus is drive fluid pressure.
154. The process as recited in claim 152, wherein said at least one parameter of said direct mechanical ventricular assistance apparatus is drive fluid flow rate.
155. The process as recited in claim 151, wherein said at least one command instruction of said algorithm maintains said function of said heart constant.
156. The process as recited in claim 151, wherein said at least one command instruction of said algorithm instructs said direct mechanical ventricular assistance apparatus to provide training to said heart.
157. The process as recited in claim 151, wherein said at least one command instruction of said algorithm instructs said direct mechanical ventricular assistance apparatus to assist in regeneration of said heart.
158. The process as recited in claim 151, wherein said exporting of said at least one command instruction instructs said displacement of said drive fluid of said direct mechanical ventricular assistance apparatus.
159. The process as recited in claim 151, wherein said exporting of said at least one command instruction instructs the delivery of a first therapeutic agent.
160. The process as recited in claim 159, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
161. The process as recited in claim 151, wherein said exporting of said at least one command instruction instructs the delivery of a first regenerative agent.
162. The process as recited in claim 161, wherein said first regenerative agent is selected from the group consisting of tissue scaffold materials, biochemical materials, stem cells, and electrical stimulation.

163. A therapeutic apparatus for delivering at least one therapeutic agent directly and preferentially to a desired tissue to be treated, comprising:
  - a. at least one membrane comprised of means to deliver said agent to said desired tissue, said membrane being in contact with at least a part of said desired tissue to be treated; and
  - b. at least one shell surrounding said membrane, said shell isolating said membrane from tissues other than said desired tissue to be treated.
164. The apparatus as recited in claim 163, wherein said at least one therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
165. The apparatus as recited in claim 163, wherein said membrane is formed as a liner.
166. The apparatus as recited in claim 165, wherein said therapeutic agent is impregnated in said membrane.
167. The apparatus as recited in claim 165, wherein said liner further comprises an impermeable film separated from said membrane by a gap, and wherein said therapeutic agent is contained in said gap.
168. The apparatus as recited in claim 165, wherein said liner is detachable from said apparatus.
169. The apparatus as recited in claim 168, wherein said at least one therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
170. The apparatus as recited in claim 165, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.

171. The apparatus as recited in claim 163, wherein said apparatus is a direct mechanical ventricular assistance apparatus.
172. The apparatus as recited in claim 171, wherein said direct mechanical ventricular assistance apparatus comprises a liner, and wherein said membrane is formed in said  
5 liner.
173. The apparatus as recited in claim 172, wherein said therapeutic agent is impregnated in said liner.
174. The apparatus as recited in claim 172, wherein said liner further comprises an impermeable film separated from said membrane by a gap, and wherein said therapeutic  
10 agent is contained in said gap.
175. The apparatus as recited in claim 172, wherein said liner is detachable from said apparatus.
176. The apparatus as recited in claim 172, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer  
15 agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
177. The apparatus as recited in claim 171, wherein said direct mechanical ventricular assistance apparatus comprises a seal, and wherein said membrane is formed in said  
20 seal.
178. The apparatus as recited in claim 177, wherein said therapeutic agent is impregnated in said seal.
179. The apparatus as recited in claim 177, wherein said seal further comprises a cavity, and wherein said therapeutic agent is contained in said cavity.
- 25 180. The apparatus as recited in claim 177, wherein said seal is detachable from said apparatus.
181. The apparatus as recited in claim 180, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer  
30 agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.

182. The apparatus as recited in claim 177, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
183. The apparatus as recited in claim 171, wherein said direct mechanical ventricular assistance apparatus comprises at least one sensor measuring at least one parameter.
184. The apparatus as recited in claim 183, wherein said direct mechanical ventricular assistance apparatus comprises a liner, and wherein said membrane is formed in said liner.
185. The apparatus as recited in claim 183, wherein said direct mechanical ventricular assistance apparatus further comprises a seal, and wherein said membrane is formed in said seal.
186. The apparatus as recited in claim 163, further comprising a second membrane comprised of means to deliver said agent to said desired tissue, said second membrane being in contact with at least a part of said desired tissue to be treated.
187. The apparatus as recited in claim 186, wherein said at least one at least one membrane is formed as a liner, and said second membrane is formed in said seal.
188. The apparatus as recited in claim 187, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
189. An apparatus for assisting the pumping of circulating blood by a heart disposed within a body, and comprising an outer wall, said apparatus comprising:
  - a. means for applying a uniform force to a portion of said outer wall of said heart by a membrane;
  - b. means to drive said membrane by cyclic application of a drive fluid thereto; and
  - c. means for cyclic pumping of said drive fluid implanted within said body, wherein said circulating blood is isolated from contact with said apparatus.



190. The apparatus as recited in claim 189, wherein said means for applying a uniform force to a portion of said outer wall of said heart is a rolling diaphragm liner, and wherein said membrane is formed in said rolling diaphragm liner.
191. The apparatus as recited in claim 189, wherein said means for cyclic pumping is a reciprocating pump.
192. The apparatus as recited in claim 191, wherein said reciprocating pump is driven by a linear actuator.
193. The apparatus as recited in claim 191, wherein said reciprocating pump is driven by a rotational reciprocator.
194. The apparatus as recited in claim 193, wherein said rotational reciprocator is a crankshaft.
195. The apparatus as recited in claim 193, wherein said rotational reciprocator is a camshaft.
196. The apparatus as recited in claim 191, wherein said reciprocating pump comprises a diaphragm.
197. The apparatus as recited in claim 191, wherein said reciprocating pump comprises a piston.
198. The apparatus as recited in claim 191, wherein said reciprocating pump is driven by a liquid-vapor phase change.
199. The apparatus as recited in claim 189, further comprising at least one sensor measuring at least one parameter.
200. The apparatus as recited in claim 189, wherein said membrane comprises of means to deliver a therapeutic agent to a desired tissue to be treated, said membrane being in contact with at least a part of said desired tissue to be treated.
201. The apparatus as recited in claim 200, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
202. The apparatus as recited in claim 189, wherein said membrane is formed in a liner, and said liner is detachable from said apparatus.

203. The apparatus as recited in claim 202, wherein said liner comprises a first therapeutic agent.
204. The apparatus as recited in claim 203, wherein said therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
205. An apparatus for assisting the function of a heart disposed within a body, and comprising an outer wall, said apparatus comprising:
  - a. a cup-shaped shell having an exterior wall, an interior wall, and an upper edge;
  - b. a liner having an outer surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined to said interior wall of said cup-shaped shell, thereby forming a cavity between said outer surface thereof and said interior wall of said shell;
  - c. a drive fluid cyclically interposed within said cavity; and
  - d. a seal comprising a base joined to said upper edge of said cup-shaped shell, a tip, and means for deploying said tip of said seal contiguously with said outer wall of said heart.
206. The apparatus as recited in claim 205, wherein said liner and said seal are unitary.
207. The apparatus as recited in claim 206, wherein said liner and said seal are formed by a molding process.
208. The apparatus as recited in claim 206, wherein said liner and said seal consist essentially of heat cured liquid silicone rubber.
209. The apparatus as recited in claim 205, wherein said means for deploying said tip of said seal contiguously with said outer wall of said heart comprises a ring disposed proximate to said tip of said seal, and a mating groove disposed in said exterior wall of said shell proximate to said upper edge of said shell.
210. The apparatus as recited in claim 209, wherein said means for deploying said tip of said seal contiguously with said outer wall of said heart further comprises a cavity disposed within said tapered midsection of said seal, and a lumen connected to said cavity and to a fluid source.
211. The apparatus as recited in claim 205, wherein said seal is biocompatible.

212. The apparatus as recited in claim 205, wherein said seal is biodegradable.
213. The apparatus as recited in claim 205, wherein said seal is detachable from said upper edge of said cup-shaped shell.
214. The apparatus as recited in claim 205, wherein said seal comprises a first therapeutic agent.
215. The apparatus as recited in claim 214, wherein said first therapeutic agent is diffused throughout said seal.
216. The apparatus as recited in claim 214, wherein said first therapeutic agent comprises a coating on the outer surface of said seal.
217. The apparatus as recited in claim 214, wherein a cavity is disposed within said seal, and said first therapeutic agent is disposed within said cavity.
218. The apparatus as recited in claim 214, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
219. The apparatus as recited in claim 214, wherein said seal comprises a second therapeutic agent.
220. The apparatus as recited in claim 205, wherein said seal has a textured outer surface.
221. An apparatus for assisting the function of a heart disposed within a body, and comprising an outer wall, said apparatus comprising:
  - a. a cup-shaped shell having an exterior wall, an interior wall, and an upper edge; and
  - b. a liner having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell, thereby forming a cavity between said outer surface thereof and said interior wall of said shell, wherein said liner is detachable from said cup-shaped shell.
222. The apparatus as recited in claim 221, wherein a drive fluid is cyclically interposed within said cavity.
223. The apparatus as recited in claim 221, wherein said liner is biocompatible.
224. The apparatus as recited in claim 221, wherein said liner is biodegradable.

225. The apparatus as recited in claim 221, wherein said liner comprises a first therapeutic agent.
226. The apparatus as recited in claim 225, wherein said first therapeutic agent is diffused throughout said liner.
- 5 227. The apparatus as recited in claim 225, wherein said first therapeutic agent comprises a coating on the inner surface of said liner.
228. The apparatus as recited in claim 225, wherein said liner comprises a first membrane and a second membrane, and said first therapeutic agent is disposed between said first membrane and said second membrane.
- 10 229. The apparatus as recited in claim 225, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
- 15 230. The apparatus as recited in claim 225, wherein said liner comprises a second therapeutic agent.
231. The apparatus as recited in claim 225, wherein said liner has a textured inner surface.
232. An apparatus for assisting the function of a heart disposed within a body, and comprising an outer wall, said apparatus comprising:
  - a. a cup-shaped shell having an exterior wall, an interior wall, and an upper edge; and
  - b. a liner having an outer surface and an inner surface, an upper edge joined to said interior wall of said cup-shaped shell, and a lower edge joined of said interior wall of said cup-shaped shell, thereby forming a cavity between said outer surface thereof and said interior wall of said shell, wherein said liner comprises a first therapeutic agent.
- 25 233. The apparatus as recited in claim 232, wherein a drive fluid is cyclically interposed within said cavity.
234. The apparatus as recited in claim 232, wherein said liner is biocompatible.
- 30 235. The apparatus as recited in claim 232, wherein said liner is biodegradable.
236. The apparatus as recited in claim 232, wherein said first therapeutic agent is diffused throughout said liner.

237. The apparatus as recited in claim 232, wherein said first therapeutic agent comprises a coating on the inner surface of said liner.
238. The apparatus as recited in claim 232, wherein said liner comprises a first membrane and a second membrane, and said first therapeutic agent is disposed between said first  
5 membrane and said second membrane.
239. The apparatus as recited in claim 232, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell  
10 engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.
240. The apparatus as recited in claim 232, wherein said liner comprises a second therapeutic agent.
241. The apparatus as recited in claim 232, wherein said liner has a textured inner surface.
- 15 242. The apparatus as recited in claim 232, wherein said liner is detachable.